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Formulation and Evaluation of Herbal Cough Syrup

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ABSTRACT:-

Cough is a common respiratory symptom that can arise from infections, allergies, or environmental irritants. Conventional cough syrups often cause drowsiness or other side effects, leading to increased interest in herbal formulations. This study aims to formulate and evaluate a herbal cough syrup using natural plant extracts and honey as the base. Medicinal herbs including Tulsi, peppermint, Adulsa powder, Clove, Fennel, Ginger, Turmeric, Honey were selected for their well-documented expectorant, antitussive, and soothing properties. Honey was incorporated not only as a sweetener but also for its demulcent and antimicrobial effects. The syrup was prepared by aqueous extraction of herbs, followed by formulation with honey and preservatives. Evaluation parameters included organoleptic properties, pH, viscosity, microbial load, stability, and total solid content. The prepared syrup was found to be stable, palatable, and free from microbial contamination, suggesting its potential as a safe and effective alternative to synthetic cough suppressants. This formulation offers a promising approach to managing cough with minimal side effects and enhanced patient compliance.

Keywords:- Cough, Herbal syrup, Herbal formulation, Herbal treatment, Antitussive.

INTRODUCTION:-

Cough is a common reflex action that serves to clear the airways of irritants, secretions, or foreign particles. It is one of the most frequent symptoms prompting patients to seek medical attention, and can result from infections, allergies, environmental factors, or underlying chronic conditions such as asthma and bronchitis.

Conventional treatment for cough often involves synthetic antitussives and expectorants, which may cause undesirable side effects like drowsiness, gastrointestinal discomfort, or dependency with prolonged use. As a result, there is a growing interest in herbal remedies that are safer, more holistic, and better tolerated, especially in children and elderly patients.

Herbal medicines have been used for centuries in traditional systems like Ayurveda, and many plant-based remedies have scientifically proven pharmacological effects. Medicinal plants such as *Ocimum sanctum* (Tulsi), *Zingiber officinale* (Ginger), *Glycyrrhiza glabra* (Liquorice), *Adhatoda vasica* (Vasa), and *Piper nigrum* (Black Pepper) exhibit properties like antitussive, expectorant, anti-inflammatory, and antimicrobial actions. These make them suitable candidates for inclusion in a polyherbal cough syrup formulation.

Honey, a natural sweetener, is not only palatable but also possesses soothing, antimicrobial, and demulcent properties. Its inclusion enhances the therapeutic potential and acceptability of the syrup, especially in pediatric populations.

This study aims to formulate and evaluate a herbal cough syrup using standardized plant extracts and honey, with the goal of offering a safe, effective, and palatable alternative to conventional cough syrups. The formulation will be assessed based on its physicochemical properties, microbial stability, and organoleptic acceptability.

Pathophysiology of Cough

Cough is a protective reflex that helps clear the respiratory tract of secretions, irritants, foreign particles, and pathogens. It involves a complex interplay between the respiratory system, nervous system, and musculoskeletal system.

1. Initiation of the Cough Reflex

The cough reflex begins when sensory receptors in the respiratory tract are stimulated by:

- Mucus accumulation
- Inflammatory mediators (e.g., histamine, prostaglandins)
- Mechanical irritants (e.g., dust, smoke)
- Chemical irritants (e.g., pollutants, acid reflux)

These receptors—mainly located in the larynx, trachea, bronchi, and sometimes the ear canal—send signals via the vagus nerve to the cough center in the medulla oblongata of the brainstem.

2. Cough Reflex Arc

The cough reflex has three major phases:

- 1. Afferent phase: Sensory nerves (vagus, glossopharyngeal, phrenic) carry impulses to the brainstem.
- 2. Central processing phase: The cough center in the medulla processes the input.
- 3. Efferent phase: Motor impulses are sent via:
 - O The phrenic nerve to the diaphragm
 - O Spinal motor nerves to intercostal and abdominal muscles
 - O Recurrent laryngeal nerve to control glottis movement

3. Execution of the Cough

The mechanical act of coughing occurs in the following sequence:

- 1. Deep inhalation
- 2. Closure of the glottis
- 3. Contraction of respiratory muscles, generating high intrathoracic pressure
- 4. Sudden opening of the glottis, resulting in explosive release of air (~100 mph), expelling mucus/irritants

4. Types of Cough Based on Pathophysiology

Type Pathophysiological Cause

Acute cough Viral infections, allergies, environmental irritants

Chronic cough Asthma, GERD, chronic bronchitis, ACE inhibitors

Productive cough Associated with mucus production (e.g., infections, bronchitis)

Dry cough Due to irritation or inflammation without mucus

5. Role of Inflammation and Mucus

In infections or allergic reactions:

- Inflammatory cytokines (IL-1, TNF-α) are released
- Goblet cells increase mucus production
- Bronchial smooth muscle may contract (bronchospasm)
- This leads to airway obstruction and triggers further coughing

Relevance to Herbal Treatment

Herbs like Tulsi, Liquorice, and Vasa act on various stages of the cough pathway:

- Reduce inflammation (anti-inflammatory action)
- Thin or reduce mucus (expectorant/mucolytic action)
- Soothe irritated mucosa (demulcent effect via honey or liquorice)
- Suppress excessive cough reflx (mild antitussive action)

Prognosis

The prognosis of a cough largely depends on its underlying cause, duration, and the effectiveness of treatment. Most **acute coughs** caused by viral infections, mild allergies, or environmental irritants are **self-limiting** and resolve within 7–10 days, especially with supportive care like herbal remedies.

Acute Cough

- $\bullet \qquad \textbf{Excellent prognosis} \text{ with appropriate treatment.}$
- Symptoms typically resolve within 1–2 weeks.
- Herbal cough syrups with ingredients like Tulsi, Ginger, and Liquorice can help relieve symptoms and shorten duration due to their antiinflammatory, soothing, and expectorant effects.

Chronic Cough

- **Prognosis depends** on the underlying condition (e.g., asthma, GERD, chronic bronchitis).
- Herbal syrups can offer symptomatic relief but may not address root causes in chronic or systemic conditions.

Infectious Coughs

- With proper management, including herbal interventions and rest, most patients recover without complications.
- Secondary bacterial infections may worsen the prognosis if untreated.

Impact of Herbal Cough Syrup on Prognosis

- Improves symptom control (e.g., reduces throat irritation, eases expectoration).
- Reduces reliance on synthetic medications, lowering risk of side effects like sedation or dependence.
- Enhances patient compliance due to better taste (with honey) and perceived safety.
- May support immune function and prevent progression to more severe respiratory conditions.

Coughs in pediatrics:-

Cough is one of the most common symptoms encountered in pediatric practice. It is usually a protective reflex that helps clear the airways of mucus, irritants, or foreign particles. In children, it can be particularly distressing due to their narrower airways, underdeveloped immune systems, and increased sensitivity to environmental triggers.

Common Causes of Cough in Children

Cause Description

Viral upper respiratory infections Most common; includes colds, flu, RSV

Allergies Triggered by dust, pollen, mold, or animal dander

Asthma Chronic inflammatory condition with recurrent wheezing and cough

Gastroesophageal reflux (GERD) Acid reflux may cause chronic cough, especially at night

Pertussis (Whooping cough) Bacterial infection that causes a characteristic "whooping" sound

Postnasal drip Often due to sinusitis or allergic rhinitis

Environmental irritants Smoke, strong odors, or air pollution

Types of Pediatric Cough

- Dry Cough: Often due to viral infections or allergies; lacks mucus production.
- Wet/Productive Cough: Indicates mucus production, common in infections like bronchitis.
- Paroxysmal Cough: Sudden, intense bouts of coughing, may be seen in pertussis.
- Chronic Cough: Lasts more than 4 weeks; needs evaluation for asthma, TB, or GERD.

Challenges in Pediatric Cough Management

- Children may not effectively expectorate mucus.
- Many synthetic cough syrups have age restrictions due to side effects like drowsiness, irritability, or toxicity.
- Over-the-counter (OTC) cough medications are not recommended for children under 6 years in many countries.

Role of Herbal Cough Syrups in Pediatrics

- Herbal syrups offer **safer alternatives** to synthetic medications.
- Ingredients like Liquorice, Tulsi, and Honey have soothing, antimicrobial, and immune-supportive effects.
- Honey has been shown in studies to reduce night-time coughing and improve sleep quality in children over one year of age.
- Herbal syrups are often better tolerated, with fewer side effects, and improved compliance due to natural flavor and sweetness.

Herbal treatment for cough:-

Herbal medicine has long been used as a natural remedy for various respiratory ailments, including cough. Unlike synthetic medications that may produce side effects such as drowsiness or dependency, herbal remedies offer a safer and often more holistic approach. Many medicinal plants possess **antitussive**, **expectorant**, **anti-inflammatory**, **bronchodilator**, and **immunomodulatory** properties, making them effective in relieving different types of cough.

Commonly Used Medicinal Herbs for Cough

Herb	Botanical Name	Properties
Tulsi	Ocimum sanctum	Antimicrobial, anti-inflammatory, immunomodulatory
Ginger	Zingiber officinale	Antitussive, anti-inflammatory, warming expectorant
Liquorice	Glycyrrhiza glabra	Soothing, mucoprotective, demulcent, mild expectorant
Turmeric	Curcumin	Anti-inflamatory, anti oxidant
Black Pepper	Piper nigrum	Bioavailability enhancer, mucolytic, antitussive
Long Pepper	Piper longum	Respiratory stimulant, expectorant

Herb	Botanical Name	Properties
Clove	Syzygium aromaticum	Antimicrobial, warming, pain-relieving
Cardamom	Elettaria cardamomum	Flavour aroma
Honey (not a herb)	_	Natural demulcent, antimicrobial, cough suppressant in children >1 yr

Mechanism of Action of Herbal Remedies

- Demulcent action: Herbs like liquorice and honey coat the throat and reduce irritation.
- Expectorant action: Vasa, ginger, and black pepper help loosen mucus and facilitate its expulsion.
- Antitussive effect: Ginger and tulsi help suppress the cough reflex without sedating the patient.
- Anti-inflammatory action: Many herbs reduce inflammation in the respiratory tract, easing breathing.
- Antimicrobial activity: Tulsi, clove, and honey help fight bacterial and viral pathogens.

Forms of Herbal Treatment

- Syrups: Palatable and easy to administer, especially to children.
- Teas/Decoctions (Kashayam): Common in traditional medicine; made by boiling herbs.
- Inhalations/Steam therapy: Using essential oils or herbal vapors.
- Lozenges: Herbal pastilles for throat relief.
- Powders/Churna: Can be mixed with honey or warm water.

Advantages of Herbal Cough Treatments

- Generally safer with fewer side effects
- Better patient compliance due to pleasant taste (especially with honey)
- Can be used **long-term** in chronic cases
- Suitable for children and the elderly
- Often provide multiple therapeutic benefits (e.g., anti-inflammatory + immune boosting)

Precautions

- Always standardize herbal extracts to ensure consistency and safety.
- Avoid honey in infants under 12 months (risk of botulism).
- Be cautious with herbs that may cause allergic reactions.
- Herbal remedies should not replace medical treatment in serious conditions like pneumonia or tuberculosis.

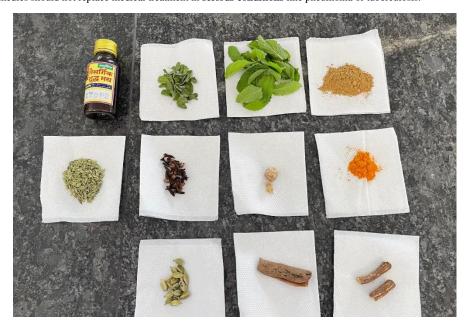


Figure 1:- Herbal ingredients used for preparation for herbal cough syrup

Formulation Table:-

Three formulation of herbal cough syrup were prepared as shown in Table 2.

Table 2:- List of herbal ingredient with quantity and use.

Sr.no	Ingredient	Quantity		Uses
		F1	F2	
1	Tulsi	15-20	15-20	Antitussive, Expectorant
		Leaves	Leaves	
2	Peppermint	2gm	2gm	Pain reliver
3	Adulsa powder	3gm	3gm	Antitussive
4	Clove	2gm	2gm	Expectorant
5	Fennel	4gm	4gm	Aromatic,flavoring agent
6	Ginger	2-3gm	2-3gm	Antitussive, Expectorant
7	Turmeric	1-2gm	1-2gm	Antitussive
8	Cardomom	2gm	2gm	Aromatic, Flavoring agent
9	Cinnamon	2gm	2gm	Aromatic, Expectorant
10	Liquorice	4gm	4gm	Expectorant
11	Honey	35%	40%	Base, Sweetener, Viscocity modifier

Method of Preparation:-

The preparation of a polyherbal cough syrup involves several key steps, including the collection and authentication of plant materials, extraction of active constituents, formulation of the syrup base, mixing, filtration, and packaging. Careful attention was paid to ensure the quality, consistency, and safety of the final product.

1. Collection and Authentication of Plant Materials

The selected medicinal plants were:

- Ocimum sanctum (Tulsi)
- Zingiber officinale (Ginger)
- Glycyrrhiza glabra (Liquorice)
- Adhatoda vasica (Vasa)
- Piper nigrum (Black Pepper)

These herbs were procured from authenticated sources and identified by a qualified botanist. Each herb was cleaned thoroughly to remove dust and foreign matter, and then shade-dried to preserve the active constituents.

2. Preparation of Herbal Extracts

A. Aqueous Extraction (Decoction Method)

- 1. Weighing: The dried plant materials were weighed accurately (quantities based on the formulation).
- 2. Crushing: The herbs were coarsely powdered using a grinder or mortar and pestle.
- 3. Boiling: The powdered herbs were mixed with a measured volume of distilled water (usually 10 times the weight of the herbs).
- 4. Heating: The mixture was boiled on low heat for about 30-45 minutes until the volume was reduced to one-third.
- 5. Cooling & Filtration: The decoction was cooled and filtered using muslin cloth or Whatman filter paper to remove plant residues.
- 6. Concentration (optional): The extract was further concentrated under reduced pressure using a rotary evaporator (if available) to obtain a semi-solid or syrup-like consistency.

3. Preparation of Syrup Base

- Honey was used as the natural sweetening and demulcent agent.
- Sucrose or invert sugar syrup may be added for additional sweetness and viscosity (optional).
- ullet Preservatives such as sodium benzoate (0.1%) were added to prevent microbial growth.
- Citric acid was added (if required) to maintain the pH and stability.
- Purified water was used as the solvent for the base.

4. Formulation of Herbal Syrup

- 1. The filtered herbal extract was slowly added to the syrup base with continuous stirring to ensure uniform mixing.
- 2. Preservatives and citric acid were added and thoroughly dissolved.
- 3. The mixture was stirred continuously until a uniform syrup consistency was obtained.
- 4. The final volume was adjusted with purified water.

5. Filtration and Bottling

• The final syrup was filtered again through a fine muslin cloth to remove any undissolved particles.

- The syrup was transferred into sterile, amber-colored glass bottles to protect from light.
- Bottles were sealed, labeled, and stored at room temperature.

6. Labeling and Storage

Each bottle was labeled with:

- Name of the formulation
- List of ingredients
- Batch number
- Date of manufacture
- Expiry date
- Dosage instructions
- Storage conditions

The syrup was stored in a cool, dry place, away from direct sunlight to ensure stability and shelf life.

Note on Dosage

The usual recommended dose for the formulated syrup was:

- Children (1–5 years): 2.5 mL twice daily
- Children (6–12 years): 5 mL twice daily
- Adults: 10 mL twice daily



Figure 2:- Extraction process(Decoction)

Evaluation parameter:-

he evaluation of a herbal cough syrup is essential to ensure its **quality**, **safety**, **efficacy**, **and stability**. The following parameters were assessed as part of the formulation development process:

1. Organoleptic Evaluation

These are the physical characteristics that influence patient compliance, especially in pediatric formulations.

Parameter	Description
Color	Visual appearance; should be uniform and appealing.
Odor	Characteristic herbal smell, free from foul odors.
Taste	Sweet, palatable, and acceptable to children.

Parameter	Description
Clarity	The syrup should be free from suspended particles or cloudiness.

2. pH Determination

- The pH of the syrup was measured using a calibrated **digital pH meter**.
- Ideal pH range: 4.0 to 6.0, which is compatible with oral formulations and prevents microbial growth.

3. Viscosity

- Viscosity influences the syrup's soothing effect and coating ability in the throat.
- Measured using a Brookfield viscometer or Ostwald's viscometer.
- The syrup should have moderate viscosity: not too thick (to pour easily), nor too thin (to remain on mucosal surfaces).

4. Specific Gravity

- Indicates the density of the syrup compared to water.
- Measured using a pycnometer.
- Ideal range: 1.20 1.35, depending on the concentration of honey and sugars.

5. Total Solid Content

- Determines the amount of dissolved solids in the syrup.
- Procedure: A known quantity of syrup is evaporated, and the remaining solid residue is weighed.
- Higher solid content indicates better stability and consistency.

6. Microbial Load Testing

- Ensures the syrup is free from harmful microorganisms.
- Tests include:
 - O Total viable bacterial count
 - O Total fungal count
 - Presence of specific pathogens like E. coli, Salmonella, Staphylococcus aureus, and Pseudomonas aeruginosa
- Must comply with WHO and IP (Indian Pharmacopoeia) microbial limits for oral preparations.

7. Stability Studies (Short-term)

- Conducted to assess the physical and chemical stability of the syrup over time.
- Parameters like pH, viscosity, color, odor, and microbial content were observed over 30–90 days under:
 - Room temperature (25°C)
 - O Accelerated conditions $(40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \text{ RH} \pm 5\%)$
- Helps in determining **shelf-life and appropriate storage conditions**.

8. Sedimentation and Syneresis

- The syrup was observed for any phase separation or sedimentation of herbal extracts.
- A good formulation remains **homogeneous** with no settling over time.

9. Refractive Index (Optional)

- Assesses the concentration and purity of sugar content.
- Determined using a refractometer.
- Helps ensure batch-to-batch consistency.

10. In-vitro Antitussive/Expectorant Activity (Optional/Advanced)

- If lab facilities are available, in-vitro screening of antitussive activity may be performed using:
 - O Isolated guinea pig trachea models
 - O Cough induction models (citric acid aerosol method)
- Expectorant activity can be tested by measuring the amount of mucus secretion in animal models.

Conclusion:-

Cough, a common symptom of respiratory tract irritation or infection, significantly affects the quality of life in both pediatric and adult populations. While it often serves as a protective mechanism, persistent coughing can become distressing and disruptive, especially in children, where it may interfere with sleep, nutrition, and school performance. The management of cough remains a critical focus in healthcare, and although synthetic cough syrups are widely used, they are frequently associated with adverse effects such as drowsiness, dry mouth, dizziness, and in some cases, allergic reactions or toxicity, particularly in children. The demand for natural, safe, and effective alternatives has led to an increased interest in herbal formulations.

This study was undertaken to formulate and evaluate a polyherbal cough syrup with honey as the base, using traditional medicinal plants known for their antitussive, expectorant, anti-inflammatory, and soothing properties. The primary herbal ingredients included. Each of these herbs has been extensively documented in Ayurvedic and traditional medicine systems, as well as in modern pharmacological studies, for their beneficial effects on the respiratory system.

The formulation process involved the aqueous extraction of the active constituents of the herbs, followed by incorporation into a syrup base consisting of purified water, honey, and suitable natural preservatives. The decision to use honey as the syrup base was deliberate and scientifically supported. Honey not only imparts a pleasant taste and acts as a natural preservative due to its antimicrobial properties but also has demulcent and cough-suppressant

effects of its own. Several studies have shown that honey is as effective as or even superior to dextromethorphan in relieving night-time cough in children above the age of one year, and it promotes better sleep quality in both children and their caregivers.

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